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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,603	02/04/2005	Hiroshi Kase	00005.001205.1	4143

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
02/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,603	KASE ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2008 has been entered.

Claim(s) 1-5 and 8-12 are pending. Claim(s) 6 and 7 have been cancelled. Claim(s) 1and 8 have been amended. Claim(s) 1-5 and 8-12 are examined herein.

Applicant's amendments have been fully considered but are not persuasive. Examiner respectfully notes that inherency is not being argued as contended by Applicant. The rejection of claims 1-5 and 8-12 are as being unpatentable over Suzuki et al. (U.S. Patent No. 5,587,378; 1996) in view of Trenkwalder (Clinical Neuroscience, 1998) is an obviousness rejection. The Examiner is maintaining the argument that Applicant's compounds which are taught by Suzuki as being administered for the treatment of Parkinson's would necessarily (not inherently) be useful in the treatment of RLS. As previously set forth on record, because Trenkwalder teaches that 60-90% of PD patients complain about a variety of disease-related or secondary mechansims of which include restless leg syndrome and/or nocturnal myoclonus it would be obvious to administer said compounds to also treat indivuals with restless syndrome or nocturnal

myoclonus because there is an overlapping population of patients that have both PD and restless leg syndrome and/or nocturnal myoclonus.

Thus, it would be obvious that by administering PD with Applicant's compound, that one would also necessarily be treating restless leg syndrome and/or nocturnal myoclonus in said overlapping population of patients.

The 103(a) rejection is hereby maintained and is modified in view of Applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (U.S. Patent No. 5,587,378; 1996) of record in view of Trenkwalder (Clinical Neuroscience, 1998) of record in further view of Evidente (*Movement Disorders*, 2000).

Suzuki teaches a method for administering xanthine derivative compounds, in particular, (E)- 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine (Example 8, column

55, lines 27-57), in an effective amount to patients suffering from Parkinson's disease (PD) (column 3, lines 34-36; claim 1). In particular, Suzuki teaches the adenosine A2 receptor antagonistic activity of the disclosed xanthine compounds (column 1, lines 64-67), meeting the limitations of claim 7.

Suzuki does not explicitly teach restless legs syndrome and nocturnal myoclonus.

Trenkwalder teaches the frequency of sleep complaints in patients with PD is estimated between 60-90% and a variety of either disease-related or secondary mechanisms and the various treatments contribute to the development of different sleep disturbances. Trenkwalder further teaches these comprise slight, fragmented sleep with increased number of arousals and awakenings, and PD-specific motor phenomena such as nocturnal immobility, rest tremor, eye-blinking, dyskinesias, and other phenomena such as periodic and nonperiodic limb movements in sleep, restless legs syndrome, fragmentary myoclonus, and respiratory dysfunction in sleep (abstract). Trenkwalder teaches that restless legs syndrome frequently occurs in patients with Parkinson's disease at an advanced stage (page 108 column 3). Further, Trenkwalder teaches that another motor phenomenon that occurs in Parkinson's disease is nocturnal myoclonus (page 108, column 3).

Evidente teaches that RLS demonstrates favorable response to antiparkinsonian medications like levodopa and dopamine agonists.

It would have been obvious to one of ordinary skill in that art at the time of the invention to have administered the compound(s) of formula I to PD patients as taught by

Suzuki and used them to also treat patients with restless legs syndrome and nocturnal myoclonus. The motivation, provided by Trenkwalder, teaches that these motor disturbances are commonly observed in individuals with Parkinson's disease. Thus if a patient with PD is administered the compound of formula I, it would be obvious that the restless legs syndrome and nocturnal myoclonus symptoms would also necessarily be treated. Additionally, in further view of Evidente, it is taught that RLS responds well to antiparkinsonian drugs such as levodopa and dopamine agonists. Thus one would be further motivated to treat RLS with Applicant's compounds because one would expect with a reasonable degree of success that because RLS responds to antiparkinsonian treatment agents such as levodopa and dopamine agonists that it would also respond to Applicant's compounds taught by Suzuki which are also antiparkinsonian agents.

Conclusion

Claims 1-5 and 8-12 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617